

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

**HAHN, Gary S. and THUESON, David O.**

**Serial No.:** To be assigned

**Filed:** November 21, 2001

**For:** TOPICAL PRODUCT  
FORMULATIONS CONTAINING  
STRONTIUM FOR REDUCING SKIN  
IRRITATION

)  
) **Group Art Unit:** To be assigned

)  
) **Examiner:** To be assigned

**PRELIMINARY AMENDMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Transmitted herewith is a Preliminary Amendment for the above-identified application, which is being filed on even date herewith.

**IN THE SPECIFICATION:**

At page 1, immediately following the title of the invention, please insert the following new paragraph:

--This application is a continuation of Serial No. 09/871,576, filed May 31, 2001, Serial No. 09/149,886, filed September 8, 1998, which is a continuation of Serial No. 08/666,978, filed June 20, 1996, and issued as U.S. Patent No. 5,804,203, which is a continuation-in-part of Serial No. 08/362,100, filed

LA-218417.1

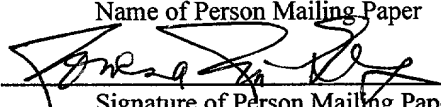
**CERTIFICATE OF MAILING**  
(37 C.F.R. §1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as 'Express Mail Post Office To Addressee' in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

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December 21, 1994 and issued as U.S. Patent No. 5,716,625. The present application claims the benefit of the filing date of Serial No. 08/362,100 (December 21, 1994), as well as the benefit of all intervening applications, pursuant to 35 U.S.C. § 120 and other applicable law, and the entire disclosures of all of these applications are incorporated herein by reference.--

At page 22, line 5, delete "attorney docket numbers 210/181, 210/182, 210/183, and 210/184,".

At page 22, line 7, delete "attorney docket number 210/290,".

At page 22, line 22, before the "DETAILED DESCRIPTION" section, please insert the following text:

**--BRIEF DESCRIPTION OF THE DRAWINGS**

FIGURES 1 through 4 depict experimental data showing the time course of irritation responses (FIG. 1), the cumulative irritation over time (FIG. 2), and the subject-by-subject cumulative irritation suppression and irritation responses (FIGS. 3 and 4) for a panel of humans treated with 250 mM strontium nitrate (and control) in a lactic acid skin irritation challenge.

FIGURES 5 through 8 depict experimental data showing the time course of irritation responses (FIG. 5), the cumulative irritation over time (FIG. 6), and the subject-by-subject cumulative irritation suppression and irritation responses (FIGS. 7 and 8) for a panel of humans treated with 250 mM strontium nitrate (and control) in a capsaicin skin irritation challenge.

FIGURES 9 through 12 depict experimental data showing the time course of irritation responses (FIG. 9), the cumulative irritation over time (FIG. 10), and the subject-by-subject cumulative irritation suppression and irritation responses (FIGS. 11 and 12) for a panel of humans treated with 250 mM strontium nitrate (and control) in a glycolic acid skin irritation challenge.

FIGURES 13 through 16 depict experimental data showing the time course of irritation differential responses (FIG. 13), the cumulative irritation

differential over time (FIG. 14), and the subject-by-subject cumulative suppression of irritation differential and irritation differential responses (FIGS. 15 and 16) for a panel of humans treated with 250 mM strontium nitrate (and control) in a benzoyl peroxide skin irritation challenge.

FIGURES 17 through 20 depict experimental data showing the time course of irritation responses (FIG. 17), the cumulative irritation over time (FIG. 18), and the subject-by-subject cumulative irritation suppression and irritation responses (FIGS. 19 and 20) for a panel of humans treated with 500 mM strontium nitrate (and control) in a post-shaving ocean water skin irritation challenge.

FIGURES 21 through 24 depict experimental data showing the time course of irritation responses (FIG. 21), the cumulative irritation over time (FIG. 22), and the subject-by-subject cumulative irritation suppression and irritation responses (FIGS. 23 and 24) for a panel of humans treated with 500 mM strontium nitrate (and control) in a post-shaving lactic acid skin irritation challenge.

FIGURE 25 depicts experimental data showing the cumulative irritation inhibition effects of strontium nitrate administered at varying concentrations (31-500 mM) in a lactic acid skin irritation challenge. --

At page 31, lines 6-7, delete "attorney docket numbers 210/181, 210/182, 210/183, and 210/184,".

At page 31, line 9, delete "attorney docket number 210/290,".

**IN THE CLAIMS:**

Please amend the claims as follows:

1. (Amended) A topical formulation for reducing skin irritation in animals comprising at least 0.5% by weight [about 0.5] to about 10% by weight of the total formulation of [an] aqueous-soluble divalent strontium cation, and a suitable topical formulation vehicle, wherein said topical formulation is packaged with instructions directing the administration of said composition to the skin of an animal subject, and wherein said formulation is effective to prevent or reduce skin irritation at the skin site where the formulation is administered.

**FOLLOWING THE CLAIMS:**

Please insert an abstract of the invention, which appears on the following separate sheet.

**--ABSTRACT**

Topical formulations containing aqueous-soluble divalent strontium cation in a suitable topical formulation vehicle, and methods of using these formulations to inhibit skin irritation, are disclosed.--

Remarks

The specification has been amended at page 1 to set forth related applications, to which the present application claims the benefit of priority.

The specification has also been amended consistent with the requirements of the Examiner as set forth in the Office action mailed September 1, 2000 in parent application Serial No. 09/149,886. Additionally, an Abstract has now been submitted.

Claim 1 has been amended to expedite examination of the present application, and in view of subject matter already allowed in related Application Serial No. 08/860,993 (now Patent No. 6,139,850).

In particular, independent claim 1 has been amended to specify that the claimed topical formulation is packaged with instructions directing that the composition be administered to animal skin, and to specify that the composition is effective to inhibit irritation at the site of administration. Support is seen in claim 69 as originally filed in parent application Ser. No. 08/362,100 (December 21, 1994 -- reciting packaging with instructions for administration), and also, for example, in the clinical tests described at pages 44-56 of the specification (anti-irritant effect measured at the site of skin administration).

It is recognized that the filing of a terminal disclaimer may be necessary in the present case, in view of applicants' already issued patents including Patent No. 6,139,850, No. 5,804,203 and No. 5,716,625. It is requested, however, that this matter be held in abeyance until such time as the subject matter has been examined against the prior art, including prior art that has already been cited in the course of the parent applications and in connection with Patent No. 6,139,850.

Respectfully submitted,

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